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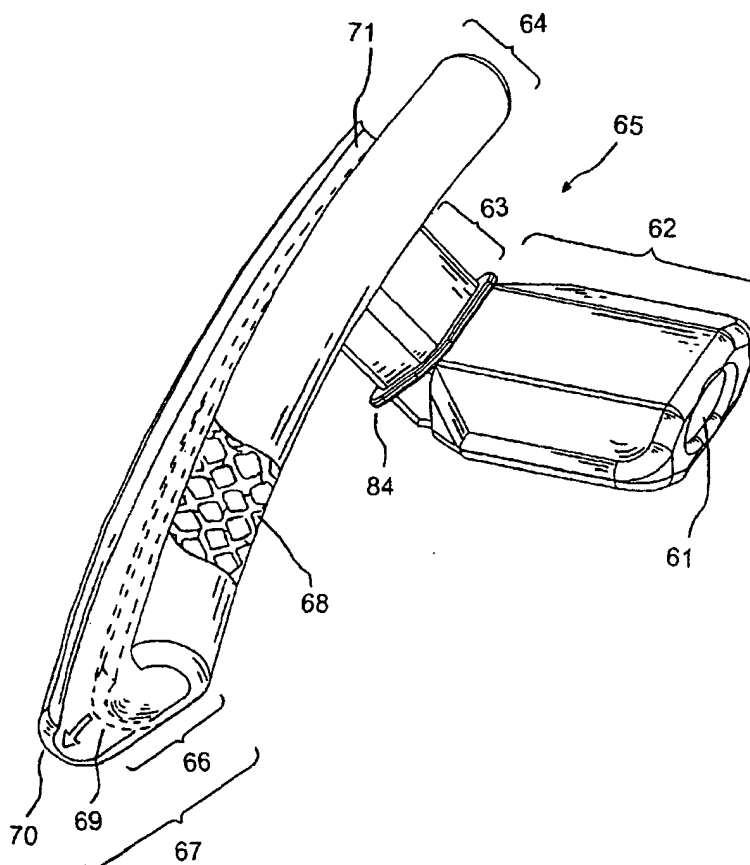
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(54) Title: STENTED TRABECULAR SHUNT AND METHODS THEREOF



(57) Abstract: A stented trabecular shunt (65) for transporting aqueous humor to bypassing diseased trabecular meshwork from an anterior chamber of an eye to an existing outflow pathway comprising an inlet section (62) and an outlet section (64), wherein the outlet section comprises a stenting element (68) that is expandable and adapted for stabilizing the outlet section within an existing outflow pathway. The stenting element may be made of a shape-memory Nitinol, the shape-memory Nitinol having a preshape and a shape transition temperature, wherein the shape-memory Nitinol expands to its preshape when the shape-memory Nitinol is heated by RF energy or an external heat source to above the shape transition temperature.

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STENTED TRABECULAR SHUNT AND METHODS THEREOF

FIELD OF THE INVENTION

5 The present invention generally relates to glaucoma devices for the reduction of ocular pressure in the anterior chamber of an eye. More particularly, the present invention relates to the treatment of glaucoma by trabecular bypass surgery and a stented trabecular shunt which bypasses diseased trabecular meshwork at the level of trabecular meshwork and restores existing outflow pathways.

BACKGROUND OF THE INVENTION

10 A stent is a generally longitudinal tubular device formed of biocompatible material, preferably a metallic or a plastic material, which is useful in the treatment of stenosis, strictures or aneurysms in body vessels such as blood vessels or Schlemm's canal of an eye. It is well known to employ a stent for the treatment of diseases of various body vessels and for stabilization the stent in a conduit. The device may be implanted within the conduit to reinforce collapsing, partially occluded, weakened or abnormally dilated sections of the conduit. One type of stents is employed after angioplasty of a blood vessel to prevent restenosis of the diseased vessel. Stents may be useful in other body
15 conduits such as the urological tract, bile duct, Schlemm's canal, or aqueous vein in an eye.

 Stents generally include an open flexible configuration. The stent configuration allows the stent to be configured in a radially or longitudinally compressed state for insertion to an appropriate site. Once properly positioned in place, the stent is expanded so as to support/reinforce the conduit or stabilize itself inside the conduit. Radial
20 expansion of the stent may be accomplished by an inflatable balloon attached to a catheter or the stent may be of the self-expanding type that will radially expand once deployed from the end portion of a delivery catheter. One stent example is U.S. Pat. No. 4,733,665 to Palmaz, which is incorporated herein by reference.

 In the aforementioned conventional process of expanding a stent, it does not provide mechanisms for axial expansion. To expand a stent or stented device in either radial or axial direction, it would be beneficial to activate the
25 expansion step by an expansion mechanism without any mechanical interference on the device, such as a balloon. To deploy an expandable stented trabecular shunt of less than one millimeter, it is very difficult to apply an inflatable balloon inside that shunt as a deploying mechanism. It is equally difficult to deliver a self-expanding stented shunt of less than one millimeter using a delivery catheter. Gentle heat may be the only means for applying to a temperature sensitive shape-memory Nitinol stent so that the stent is expanded at a temperature above its shape-memory
30 transitional temperature.

 In a copending patent application Ser. Nr. 09/549,350, filed 4/14/2000, entitled "Apparatus and method for treating glaucoma", a glaucoma device is disclosed for transporting the aqueous humor to bypassing diseased trabecular meshwork at a level of the trabecular meshwork and using existing outflow pathways. The glaucoma device may comprise an elongated tubular element having an outlet section and an inlet section, wherein the outlet
35 section is positioned inside the existing outflow pathway, such as Schlemm's canal. The outlet section of the

glaucoma device inside Schlemm's canal may be stented so as to stabilize the device at its implanted location. The co-pending application (09/549,350) is incorporated herein by reference.

5 The human eye is a specialized sensory organ capable of light reception and able to receive visual images. The main parts of the eye are the cornea, the iris, the lens, the retina, the trabecular meshwork, and outflow pathways, such as Schlemm's canal. The trabecular meshwork serves as a drainage channel located between the cornea and the surrounding white portion of the eye. The trabecular meshwork maintains a balanced pressure in the anterior chamber of the eye by draining excess aqueous humor.

10 About two percent of people in the United States have glaucoma. Glaucoma is a group of eye diseases encompassing a broad spectrum of clinical presentation, etiology and treatment modality that causes pathological changes in the optic disk and corresponding visual field loss resulting in blindness if untreated. Intraocular pressure elevation is the major treatable etiologic factor in all glaucomas.

15 In glaucomas associated with an elevation in eye pressure the source of resistance to outflow is mainly in the trabecular meshwork. The tissue of the trabecular meshwork allows the "aqueous" to enter Schlemm's canal, which then empties, into aqueous collector channels in the posterior wall of Schlemm's canal and then into aqueous veins. The aqueous or aqueous humor is a transparent liquid that fills the region between the cornea at the front of the eye and the lens. The aqueous humor is constantly secreted by the ciliary body around the lens, so there is a continuous flow of the aqueous humor from the ciliary body to the eye's front chamber. The eye's pressure is determined by a balance between the production of aqueous and its exit through trabecular meshwork (major route) or uveal scleral outflow (minor route). The trabecular meshwork is located between the outer rim of the iris and the back of the cornea. The portion of the trabecular meshwork adjacent to Schlemm's canal causes most of the resistance to aqueous outflow (juxtacanalicular meshwork).

20 Therefore, there is a great clinical need for the treatment of glaucoma by a method that would be faster, safer and less expensive than currently available modalities. Trabecular bypass surgery is an innovative surgery which uses a trabecular shunt device to bypass diseased trabecular meshwork alone at the level of trabecular meshwork and use/restore existing outflow pathways. The object of the present invention is to provide a stented trabecular shunt and methods for treating elevated intraocular pressure in a manner which is simple, effective, disease site-specific and can be performed on an outpatient basis. The stenting portion of the trabecular shunt is to be deployed by gentle heat and adapted to stabilize the shunt inside Schlemm's canal even under constant movement of the eye lens.

Summary of the Invention

30 In general, it is an object of the present invention for the treatment of glaucoma by trabecular bypass surgery and a stented trabecular shunt which bypasses diseased trabecular meshwork at the level of trabecular meshwork and restores existing outflow pathways. It is another object to provide a method for placing the stented trabecular shunt for transporting aqueous humor to bypassing diseased trabecular meshwork. It is a further object of the present invention to provide a stented trabecular shunt comprising an inlet section and an outlet section, wherein the outlet

section comprises a stenting element that is retractable/expandable and adapted for stabilizing the outlet section within an existing outflow pathway for aqueous humor disposition.

5 In one preferred embodiment, the stenting element may be made of a shape-memory Nitinol. The shape-memory Nitinol has a preshape and a shape transition temperature, wherein the crimped shape-memory Nitinol expands to its preshape when the shape-memory Nitinol is heated to above the shape transition temperature. The shape transition temperature for the shape-memory Nitinol is preferably between about 40°C and 90°C. The transition temperature is further preferred between about 40°C and about 50°C. A Nitinol device is well known to have a preshape and a transition temperature for the Nitinol device to reverse to its preshape.

10 The stenting element may be expanded by heat above the shape transition temperature. In one embodiment, a source of RF energy is adapted for delivering RF energy through an electrical conductor to the stenting element and heating the stenting element to above the shape transition temperature of the shape-memory Nitinol. The RF current is preferably within the range of 50 to 2,000 kHz. In another embodiment, an external heat source is provided and adapted for heating the stenting element to above the shape transition temperature of the shape-memory Nitinol.

15 The stenting element in this invention may include a permanent implantable stent, or a temporary stent, wherein the temporary stent is defined in this invention as a stent that is expandable inside a conduit and removed thereafter from the conduit of a patient. The configuration of the stenting element may be selected from a group consisting of a coil stent, a Nitinol stent, a mesh stent, a scaffold stent, a sleeve stent, a permeable stent, a porous stent made of porous material for drug delivery, a U-shape stent, a combination of the above, and the like.

20 In a preferred embodiment, the exterior surface of the stenting element of the present invention may have fluorine-containing coating. The exterior surface of a stenting element having fluorine-containing compound is to render the tissue-contacting surface biocompatible. It is well known to one who is skilled in the art that a fluorinated surface has low surface energy and is highly biocompatible and hemo-compatible. The "fluorine-containing surface" is synonymous in this invention to "fluorinated surface", which substrate surface is covered or impregnated with fluorine, fluoride, other fluorine-containing compounds, and the like. The fluorine-containing coating and its process may be selected from a group consisting of glow discharge coating, adhesive coating, impregnating coating, compound coating, dip coating, paste coating, and sintering. The dip coating and paste coating on a metallic substrate followed by sintering has been extensively used to coat the frying pans and the like, and is well known to one who is skilled in the art. One class of the fluorine-containing material used in the coating process has a tradename of Teflon® (a tradename of Du Pont Company).

30 In an additional alternate embodiment, the stenting element is embedded within a biocompatible material selected from a group consisting of silicone, polyurethane, porous material, expanded polytetrafluoroethylene, semi-permeable membrane, elastomer, and mixture of said biocompatible material thereof. The embedding material usually obstructs very little to the expansion process of the stenting element.

35 The trabecular shunt of the present invention may further comprise a lumen throughout the inlet section and the outlet section for transporting aqueous humor to bypassing diseased trabecular meshwork from an anterior

chamber of an eye to the existing outflow pathway. The outlet section may comprise at least one opening for venting aqueous humor. The at least one opening is connected to and in communication with the lumen of the trabecular shunt. Furthermore, the outlet section may comprise an elongated trough along the outlet section for venting aqueous humor into the existing outflow pathway, wherein the elongated trough is connected to and in communication with the lumen of the trabecular shunt.

In accordance with the present invention, the trabecular shunt may be made of a biocompatible material selected from a group consisting of semi-permeable polymer, polyvinyl alcohol, polyvinyl pyrrolidone, collagen, heparinized collagen, polytetrafluoroethylene, expanded polytetrafluoroethylene, fluorinated polymer, fluorinated elastomer, flexible fused silica, polyolefin, polyester, polyimide, polysilicon, silicone, polyurethane, Nylon, polypropylene, hydroxyapatite, precious metal, and mixture of said biocompatible material thereof.

A method of placing a trabecular shunt for transporting aqueous humor to bypassing diseased trabecular meshwork may comprise the steps of (a) creating an opening through diseased trabecular meshwork; (b) advancing the outlet section through the opening into the existing outflow pathway; and (c) expanding the stenting element for stabilizing the outlet section within the existing outflow pathway.

In an alternate embodiment, a method of delivering a trabecular shunt to bypassing diseased trabecular meshwork, the trabecular shunt comprises an inlet section and an outlet section, wherein the outlet section comprises a stenting element that is retracted during a delivery phase. The method may comprise the steps of (a) creating an opening through diseased trabecular meshwork at a size for the outlet section with a retracted stenting element to pass through; (b) advancing the outlet section through the opening into an existing outflow pathway; and (c) expanding the retracted stenting element for stabilizing the outlet section within the existing outflow pathway.

The method and the retractable/expandable trabecular shunt of the present invention have several significant advantages over other known systems to treat the glaucoma. In particular, the stented trabecular shunt and methods for treating elevated intraocular pressure in a manner that the stenting portion of the trabecular shunt is to stabilize the shunt inside Schlemm's canal even under constant movement of the eyeball.

Brief Description of the Drawings

Additional objects and features of the present invention will become more apparent and the invention itself will be best understood from the following Detailed Description of Exemplary Embodiments, when read with reference to the accompanying drawings.

FIG. 1 is a sectional view of a stenting element having expandable/retractable capabilities at a retracted state constructed in accordance to the principles of the present invention.

FIG. 2 is an exterior sectional view of a stenting element having expandable/retractable capabilities at a radially expanded state, constructed in accordance to the principles of the present invention.

FIG. 3 is a sectional view of an eye for illustration purposes.

FIG. 4 is a close-up sectional view, showing the anatomical diagram and relative locations of the trabecular meshwork, Schlemm's canal and the anterior chamber of an eye.

FIG. 5 is an embodiment of the stented trabecular shunt device constructed according to the principles of the invention.

FIG. 6 is a schematic diagram of RF energy delivery mechanism as one method for activating the expansion/retraction of the stented trabecular shunt.

5 FIG. 7 is a perspective view of a stented trabecular shunt that has its outlet section radially expanded for stabilization itself inside Schlemm's canal.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Referring to FIGS. 1 to 7, what is shown is an embodiment of a stented trabecular shunt for transporting aqueous humor to bypassing diseased trabecular meshwork at the level of trabecular meshwork and restores existing outflow pathways and methods thereof.

10 FIG. 1 shows a section of the stenting element 43 having a crimping or collapsing capability at a non-deployed state, constructed in accordance to the principles of the present invention. As shown in FIG. 1, the stenting element 43 has its radially outer boundaries 44A, 44B at a non-deployed state. These outer boundaries 44A, 44B at a non-deployed state is smaller than the radially boundaries 44C, 44D at a deployed state of FIG. 2. When the stenting element 43 is to be collapsed, the outer boundaries at a collapsed/retracted state is smaller than the expanded boundaries 44C, 44D so that the stenting element can be delivered at its smallest size through diseased trabecular meshwork into the existing outflow pathway of an eye. The interior luminal portion 45A, 45B is to contact a body fluid, such as aqueous humor in an existing outflow pathway, while the exterior portion 46A, 46B is to contact tissue when the stenting element 43 is deployed to support and stabilize the outlet section of the stented trabecular shunt inside an existing outflow pathway, such as Schlemm's canal.

20 FIG. 2 shows an exterior sectional view of a stenting element having expandable/retractable capabilities at a radially expanded state, constructed in accordance to the principles of the present invention. As shown in FIG. 2, the stenting element 43 has its radially outer boundaries 44C, 44D at an expanded or deployed state. The exterior surface 46A, 46B is to contact tissue when the stenting element 43 is deployed to support and stabilize the outer section of the trabecular shunt inside an existing outflow pathway.

25 For background illustration purposes, FIG. 3 shows a sectional view of an eye 10, while FIG. 4 shows a close-up view, showing the relative anatomical locations of trabecular meshwork, the anterior chamber, and Schlemm's canal. Thick collagenous tissue known as sclera 11 covers the entire eye 10 except that portion covered by the cornea 12. The cornea 12 is a thin transparent tissue that focuses and transmits light into the eye and the pupil 14 which is the circular hole in the center of the iris 13 (colored portion of the eye). The cornea 12 merges into the sclera 11 at a juncture referred to as the limbus 15. The ciliary body 16 begins internally in the eye and extends along the interior of the sclera 11 and becomes the choroid 17. The choroid 17 is a vascular layer of the eye underlying retina 18. The optic nerve 19 transmits visual information to the brain and is sequentially destroyed by glaucoma.

The anterior chamber 20 of the eye 10, which is bound anteriorly by the cornea 12 and posteriorly by the iris 13 and lens 26, is filled with aqueous. Aqueous is produced primarily by the ciliary body 16 and reaches the anterior chamber angle 25 formed between the iris 13 and the cornea 12 through the pupil 14. In a normal eye, the aqueous is removed through the trabecular meshwork 21. Aqueous passes through trabecular meshwork 21 into Schlemm's canal 22 and thereafter through the aqueous veins 23 which merge with blood-carrying veins and into venous circulation. Intraocular pressure of the eye is maintained by the intricate balance of secretion and outflow of the aqueous in the manner described above. Glaucoma is characterized by the excessive buildup of aqueous fluid in the anterior chamber 20 which produces an increase in intraocular pressure (fluids are relatively incompressible and pressure is directed equally to all areas of the eye).

As shown in FIG. 4, the trabecular meshwork 21 constitutes a small portion of the sclera 11. It is understandable that creating a hole or opening for implanting a device through the tissues of the conjunctiva 24 and sclera 11 is relatively a major surgery as compared to a surgery for implanting a shunt through the trabecular meshwork 21 only. A device 65 of the present invention for either using and/or restoring existing outflow pathways positioned through the trabecular meshwork 21 is illustrated in FIG. 7.

FIG. 5 is an embodiment of the stented trabecular shunt device constructed according to the principles of the invention. A stented trabecular shunt 65 for transporting aqueous humor to bypassing diseased trabecular meshwork comprises an inlet section 62 and an outlet section 64, wherein the outlet section 64 comprises a stenting element 68 that is expandable/crippable and adapted for stabilizing the outlet section 64 within an existing outflow pathway for aqueous humor disposition. In an alternate embodiment, an optional middle section 63 is located between the inlet section 62 and the outlet section 64.

An optional ridge or flange 84 at about the junction of the inlet section 62 into the trabecular meshwork is provided for device placement purposes. The appropriate length of the inlet section may be between about 300 microns to 2 millimeters. The inlet section may be at an angle to the outlet section 64 so that the inlet end of the inlet section is safely positioned inside the anterior chamber. The inlet section 62 has an outer diameter generally around 100 microns to 1 millimeter while the lumen 61 is preferably between 50 microns to about 300 microns. The outlet section 64 is about perpendicular to or at an angle with the inlet section 62 so that the outlet section is placed inside an existing outflow pathway, such as Schlemm's canal without excess stress. The outlet section has a length of between about 200 microns to about 2 millimeters. The diameter of the outlet section may be about 100 microns to about 1 millimeter.

The stenting element 68 may be made of a shape-memory Nitinol. The shape-memory Nitinol has a preshape to form an expanded structure 67 and a shape transition temperature. During the delivery stage or non-deployed state, the shape-memory Nitinol is crimped at a retracted structure 66 for easy insertion through the trabecular meshwork. The shape-memory Nitinol expands to its preshape 67 when the shape-memory Nitinol is heated to above the shape transition temperature. As shown in FIG. 5, a retracted side 69 of the stenting element at a non-deployed state is expanded to the expanded side 70 of the stenting element at the deployed state. The "deployed state" in this

invention refers to the preshape of the shape-memory Nitinol after a temperature above its shape transition temperature is reached. Heat can also be provided from an external heat sources, such as a heating pad, a warm cloth, a bag of warm water, remotely deliverable heat, electromagnetic force, and the like.

5 In a further embodiment, the stented trabecular shunt comprises a lumen 61 throughout the inlet section 62, the optional middle section 63, and the outlet section 64 for transporting aqueous humor to bypassing diseased trabecular meshwork 21 from an anterior chamber 20 of an eye to the existing outflow pathway 22. The outlet section may comprise at least one opening for venting aqueous humor, the at least one opening being connected to and in communication with the lumen of the trabecular shunt. In a still further embodiment, the outlet section 64 may comprise an elongated opening, trough, or groove 71 along an axis of the outlet section 64 for venting aqueous humor
10 into the existing outflow pathway. The elongated trough 71 is connected to and in communication with the lumen 61 of the trabecular shunt 65.

FIG. 6 shows a schematic diagram of a RF generating means for causing the stenting element of the outlet section to expand radially, circumferentially, axially, or combination thereof. The direction of expansion is related to the design of the stenting element and type of shape-memory Nitinol used. A RF generator 51 is connected to an
15 expandable/retractable outlet section 64 of a stented trabecular shunt 65 through an electrical guidewire conductor 52. In one embodiment, the stenting element 68 is to contact the underlying tissue of the Schlemm's canal 22 at a non-deployed state. A DIP (dispersive indifferent pad) type pad 56, that contacts a patient, is connected to the Indifferent Electrode Connector on the RF generator 51. Therefore, the RF energy delivery becomes effective when a close circuit from a RF generator 51 through a stenting element, a patient and returning to the RF generator is formed.
20 A temperature sensor 57 may also used to measure the tissue temperature and is relayed through a temperature sensing wire 58 and a closed-loop temperature controller 59 for controlling the RF energy delivered. Heat to the tissue is controlled by the power of the RF energy delivered and by the delivery duration. The heat 53 to stented outlet section causes the outlet section to expand 55 when a stenting element needs to be expanded for stabilizing itself inside a confined conduit.

25 The stenting element portion of the stented trabecular shunt may comprise the fluorine-containing coating to render the surface more biocompatible, wherein the coating may be selected from a group consisting of glow discharge coating, adhesive coating, impregnating coating, compound coating, dip coating, paste coating, and sintering. The fluorination process via glow discharge method is well known to one who is skilled in the art.

FIG. 7 shows a perspective view of a stented trabecular shunt 65 that has its outlet section 64 radially
30 expanded for stabilization itself inside Schlemm's canal 22. In an alternate embodiment, the expandable outlet section can be expanded longitudinally along an axis of the outlet section 64 or a combination of radial and longitudinal expansion. A method of placing a trabecular shunt 65 for transporting aqueous humor to bypassing diseased trabecular meshwork 21 may comprise the steps of: (a) creating an opening through diseased trabecular meshwork 21 so that the outlet section 64 can pass through; (b) advancing the outlet section 64 through the opening into the
35 existing outflow pathway; and (c) expanding the stenting element from a retracted/crimped position 66 to an

expanded/deployed position 67 for stabilizing the outlet section 64 within the existing outflow pathway. In a preferred embodiment, the existing outflow pathway is Schlemm's canal 22, wherein aqueous duct 23 located at the internal portion 82 of the sclera transports the aqueous humor out of the Schlemm's canal 22. The purpose of trough 71 at the rear side of the outlet section 64 is provided and adapted not to interfere the outflow aqueous duct 23.

5 Alternately, the trabecular shunt comprises an inlet section and an outlet section, wherein the outlet section comprises a stenting element that is retracted/crimped during a delivery phase. A method of delivering a trabecular shunt to bypassing diseased trabecular meshwork may comprise the steps of: (a) creating an opening through diseased trabecular meshwork at a size just enough for the outlet section with a retracted stenting element to pass through; (b) advancing the outlet section through the opening into an existing outflow pathway; and (c) expanding the
10 retracted/crimped stenting element for stabilizing the outlet section within the existing outflow pathway

From the foregoing description, it should now be appreciated that a stented trabecular shunt and methods thereof have been disclosed. While the invention has been described with reference to a specific embodiment, the description is illustrative of the invention and is not to be construed as limiting the invention. Various modifications and applications may occur to those who are skilled in the art, without departing from the true spirit and scope of the
15 invention, as described by the appended claims.

WHAT IS CLAIMED IS:

1. A trabecular shunt for transporting aqueous humor to bypassing diseased trabecular meshwork comprising an inlet section and an outlet section, wherein said outlet section comprises a stenting element that is expandable and adapted for stabilizing said outlet section within an existing outflow pathway for aqueous humor disposition.
2. A trabecular shunt according to claim 1, wherein said stenting element is made of a shape-memory Nitinol, the shape-memory Nitinol having a preshape and a shape transition temperature, wherein the shape-memory Nitinol expands to its preshape when said shape-memory Nitinol is heated to above the shape transition temperature.
3. A trabecular shunt according to claim 1, wherein the shape transition temperature for said shape-memory Nitinol is preferably between 40°C and 90°C.
4. A trabecular shunt according to claim 1, wherein surface of the stenting element is covered with fluorine-containing compound.
5. A trabecular shunt according to claim 1, wherein said stenting element is embedded within a biocompatible material selected from a group consisting of silicone, polyurethane, porous material, expanded polytetrafluoroethylene, semi-permeable membrane, elastomer, and mixture of said biocompatible material thereof.
6. A trabecular shunt according to claim 1, wherein said existing outflow pathway is Schlemm's canal.
7. A trabecular shunt according to claim 2 further comprising a source of RF energy adapted for delivering RF energy through an electrical conductor to said stenting element and heating the stenting element to above the shape transition temperature of said shape-memory Nitinol.
8. A trabecular shunt according to claim 2, wherein an external heat source is provided and adapted for heating the stenting element to above the shape transition temperature of said shape-memory Nitinol.
9. A trabecular shunt according to claim 1, wherein said trabecular shunt comprises a lumen throughout the inlet section and the outlet section for transporting aqueous humor to bypassing diseased trabecular meshwork from an anterior chamber of an eye to the existing outflow pathway.
10. A trabecular shunt according to claim 9, wherein said outlet section comprises at least one opening for venting aqueous humor, said at least one opening being connected to and in communication with said lumen of the trabecular shunt.
11. A trabecular shunt according to claim 9, wherein said outlet section comprises an elongated trough along the outlet section for venting aqueous humor into said existing outflow pathway, said elongated trough being connected to and in communication with said lumen of the trabecular shunt.
12. A trabecular shunt according to claim 1, wherein the trabecular shunt is made of a biocompatible material selected from a group consisting of semi-permeable polymer, polyvinyl alcohol, polyvinyl pyrrolidone, collagen, heparinized collagen, polytetrafluoroethylene, expanded polytetrafluoroethylene, fluorinated polymer, fluorinated

elastomer, flexible fused silica, polyolefin, polyester, polyimide, polysilicon, silicone, polyurethane, Nylon, polypropylene, hydroxyapatite, precious metal, and mixture of said biocompatible material thereof.

5 13. A method of placing a trabecular shunt for transporting aqueous humor to bypassing diseased trabecular meshwork, the trabecular shunt comprising an inlet section and an outlet section, wherein said outlet section comprises a stenting element that is expandable and adapted for stabilizing said outlet section within an existing outflow pathway; the method comprising steps of:

- (a) creating an opening through diseased trabecular meshwork;
 - (b) advancing the outlet section through said opening into said existing outflow pathway; and
 - (c) expanding said stenting element for stabilizing said outlet section within the existing
- 10 outflow pathway.

14. A method of placing a trabecular shunt for transporting aqueous humor to bypassing diseased trabecular meshwork of claim 13, wherein said stenting element is made of a shape-memory Nitinol that has a preshape and a shape transition temperature; the method of expanding said stenting element comprising heating said shape-memory Nitinol to above the shape transition temperature.

15 15. A method of placing a trabecular shunt for transporting aqueous humor to bypassing diseased trabecular meshwork of claim 13, wherein said existing outflow pathway is Schlemm's canal.

16. A method of placing a trabecular shunt for transporting aqueous humor to bypassing diseased trabecular meshwork of claim 14, wherein the method of heating said shape-memory Nitinol comprises delivering RF energy from an external RF energy source through an electrical conductor to said stenting element and heating the

20 stenting element to above the shape transition temperature of said shape-memory Nitinol.

17. A method of placing a trabecular shunt for transporting aqueous humor to bypassing diseased trabecular meshwork of claim 14, wherein the method of heating said shape-memory Nitinol comprises an external heat source adapted for heating the stenting element to above the shape transition temperature of said shape-memory Nitinol.

25 18. A method of delivering a trabecular shunt to bypassing diseased trabecular meshwork, the trabecular shunt comprising an inlet section and an outlet section, wherein said outlet section comprises a stenting element that is retracted during a delivery phase; the method comprising steps of:

- (a) creating an opening through diseased trabecular meshwork at a size for the outlet section with a retracted stenting element to pass through;
 - (b) advancing the outlet section through said opening into an existing outflow pathway; and
 - (c) expanding said retracted stenting element for stabilizing the outlet section within the
- 30 existing outflow pathway.

19. A method of delivering a trabecular shunt to bypassing diseased trabecular meshwork of claim 18, wherein said stenting element is made of a shape-memory Nitinol that has a preshape and a shape transition

temperature; the method of expanding said retracted stenting element comprising heating said shape-memory Nitinol to above the shape transition temperature.

20. A method of delivering a trabecular shunt to bypassing diseased trabecular meshwork of claim 19, wherein the method of heating said shape-memory Nitinol comprises an external heat source adapted for heating the stenting element to above the shape transition temperature of said shape-memory Nitinol.
- 5

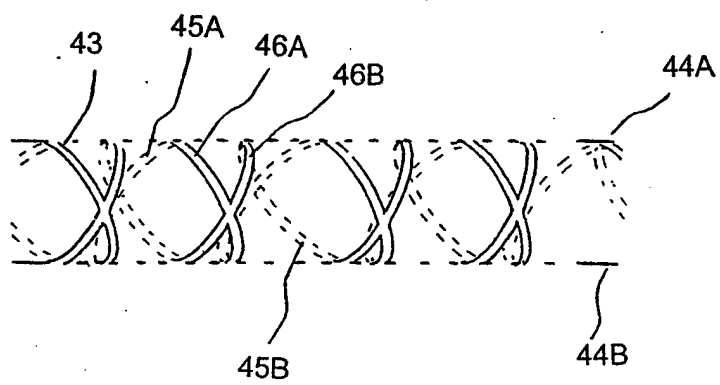


FIG. 1

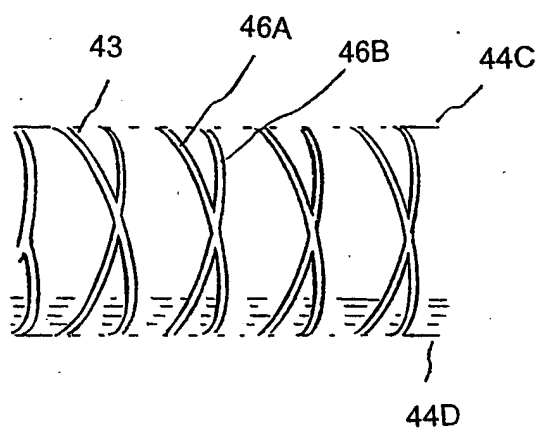


FIG. 2

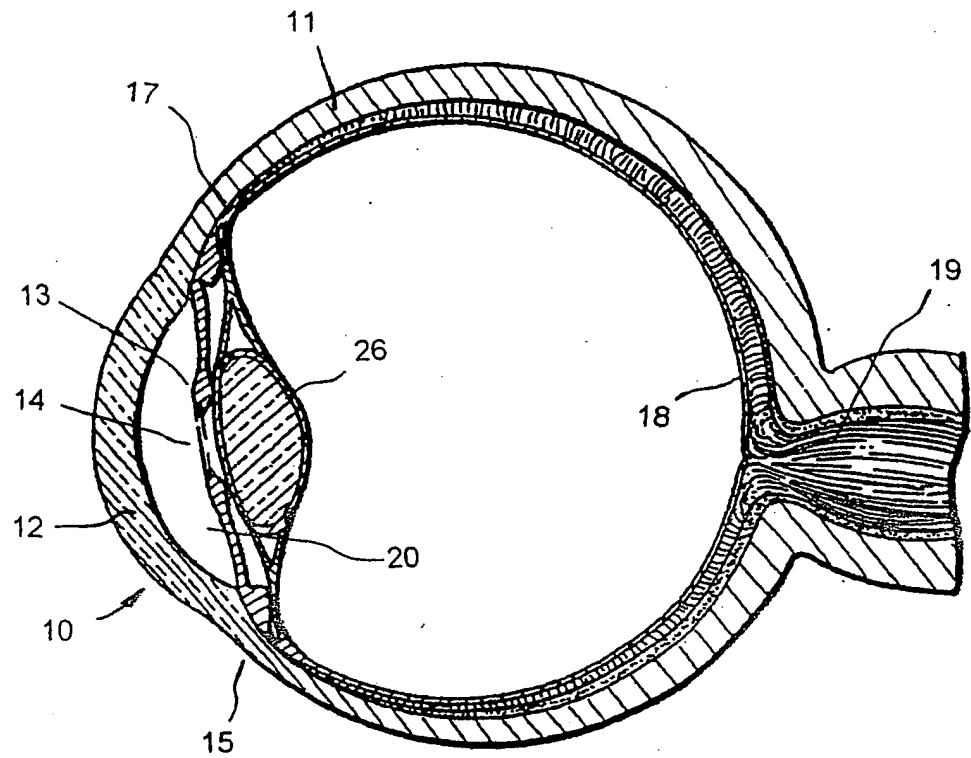


FIG. 3

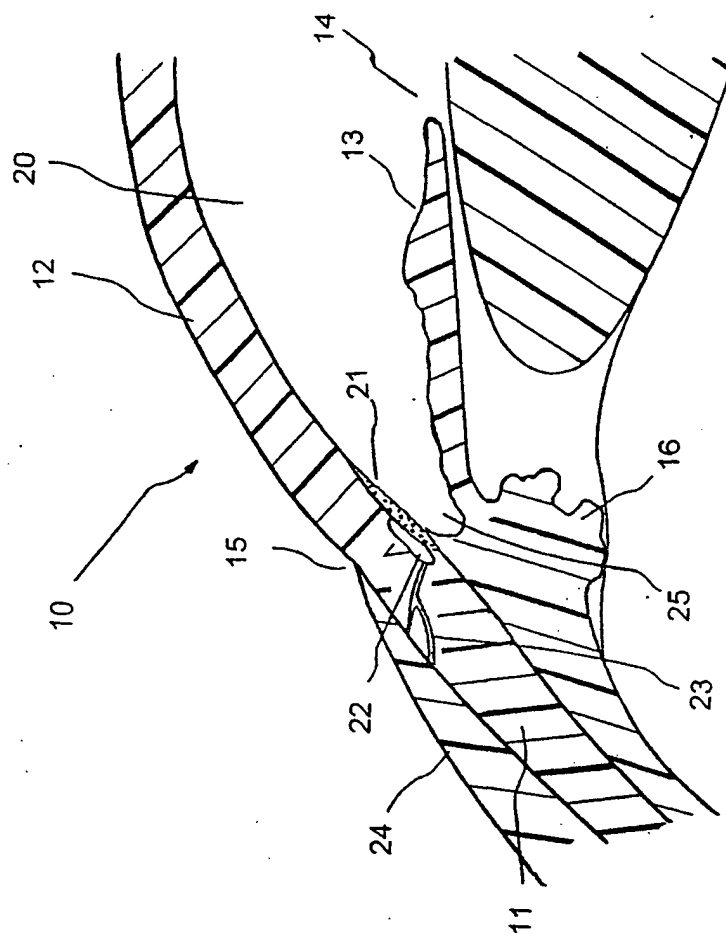


FIG. 4

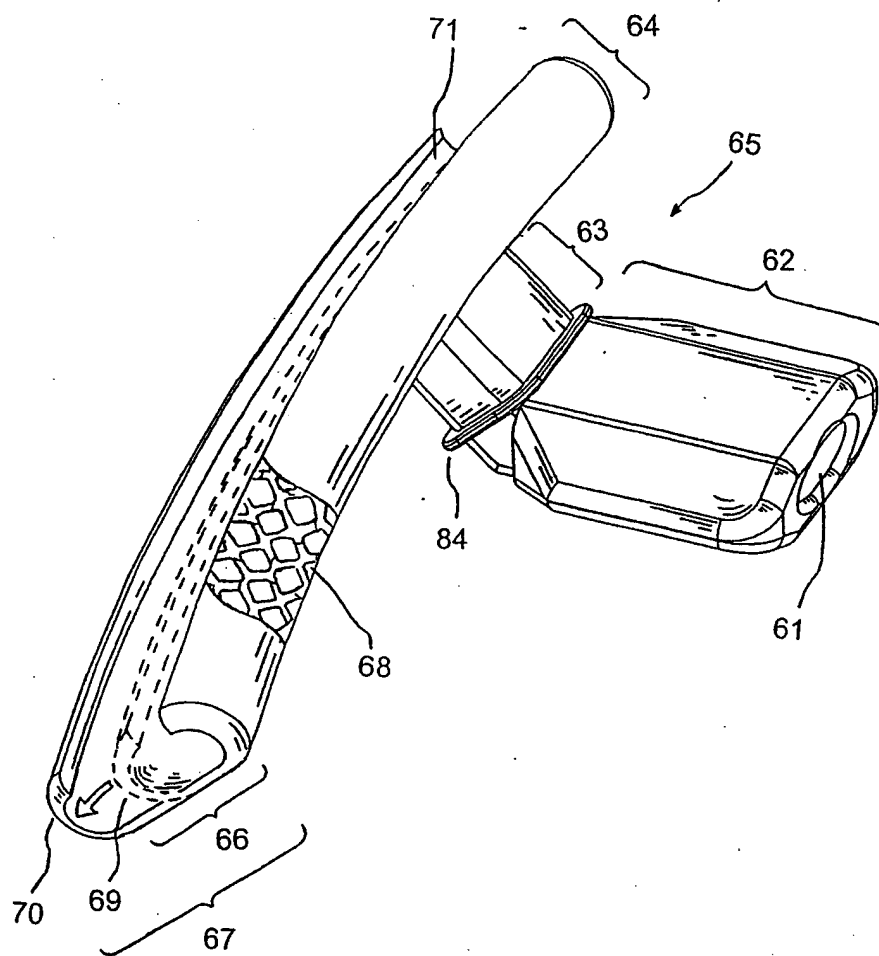


FIG. 5

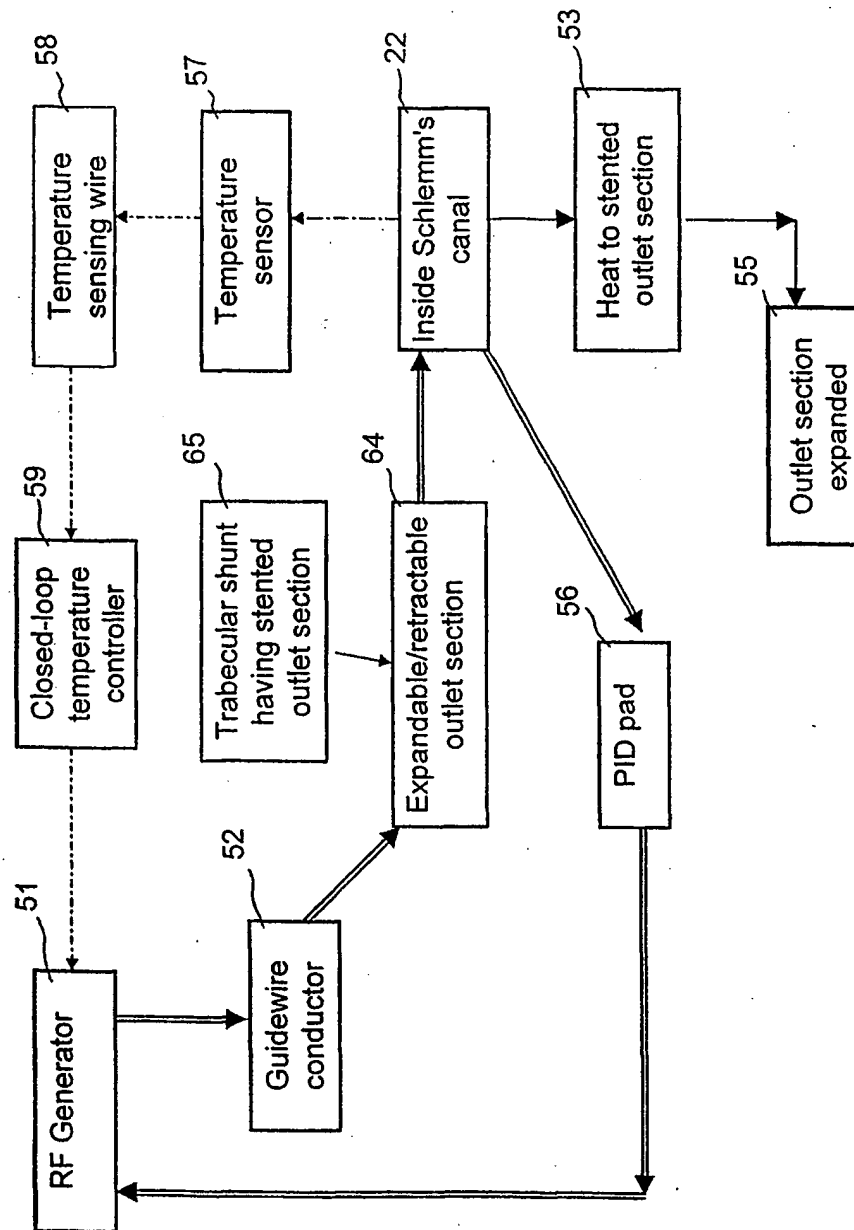


FIG. 6

INTERNATIONAL SEARCH REPORT

Int. Application No

PCT/US 01/18541

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F9/007

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	EP 0 898 947 A (GRIESHABER & CO AG) 3 March 1999 (1999-03-03)	1-3, 6, 9,
Y	column 6, line 18 - line 41; figure 11	10, 12
Y	WO 99 26567 A (OPTONOL LTD ; YARDEN ORIT (IL); YARON IRA (IL); WERNER MARY C (US)) 3 June 1999 (1999-06-03) page 24, line 13 - line 19	4, 5
A	US 5 180 362 A (WORST J G F) 19 January 1993 (1993-01-19) abstract; figures 11, 12	1
A	WO 99 30641 A (PROLIFIX MEDICAL INC) 24 June 1999 (1999-06-24) page 14, line 22 - line 32	7, 8
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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

9 October 2001

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INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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